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Effect of Valsartan in Ventricular Function and Aortic Elasticity

Submission date	Recruitment status
20/01/2006	No longer recruiting
Registration date	**Overall study status**
17/05/2006	Completed
Last Edited	**Condition category**
11/01/2021	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2002P-000067

Study information

Scientific Title

Effect of Valsartan in Ventricular Function and Aortic Elasticity

Study objectives
The primary hypothesis is that left ventricular function is impaired in diabetes, even in the absence of coronary artery disease. Protein kinase C (PKC) activation and endothelial dysfunction are the main factors that have been implicated in this. Valsartan may improve left ventricular function in the early stages and therefore, can be of help in patients without clinical cardiac abnormalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, first approved 23/01/2003

Study design
This is a randomized, double-blind, placebo-controlled, crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes mellitus type 2

Interventions
Participants will be followed up for approximately 14 months. Each participant will be randomized to either placebo or Valsartan 160 mg/day for the first six months and then given the opposite treatment for the next six months. An eight-week wash out period (up to 4-6 months) will separate the two treatment periods. MRI of the heart and aorta will be performed at baseline and the end of each period of the study.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Valsartan

Primary outcome measure
Changes in aortic elasticity (arterial compliance, stiffness index and pulse wave velocity) measured by MRI

Secondary outcome measures
Changes in ventricular function (the volumetric assessment of mass, end-diastolic and end-systolic volumes, ejection fraction (EF), stroke volume and cardiac output of the left and the right ventricles)

Overall study start date
26/02/2003

Completion date
30/06/2007

Eligibility

Key inclusion criteria
We plan to study two groups with 15 subjects each:
1. Healthy non-diabetic subjects
2. Patients with type 2 diabetes with no severe long-term diabetes complications

For inclusion in the trial, patients must fulfil all of the following criteria:
1. All subjects will be ages 21-80 years
2. Healthy subjects - subjects should not be considered at higher risk than the general population to develop type 2 diabetes according to one of the following criteria:
a. Fasting plasma glucose <100 mg/dl and/or a 2-hour plasma glucose <140 during 75 gm oral glucose tolerance test (OGTT)
3. Patients with type 2 diabetes with no serious long-term complications
4. Individuals with a diagnosis of type 2 diabetes according to the American Diabetes Association criteria below, established in 1998. Subjects previously diagnosed with type 2 diabetes will not require a repeated diagnostic testing.
a. Unequivocal elevated plasma glucose level >200 mg/dl with symptoms suggestive of hyperglycemia (polyuria, polydipsia, weight loss)
b. Fasting plasma glucose levels >126 mg/dl
c. Two-hour plasma glucose >200 mg/dl during a 75 gm OGTT
In the absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day.
5. Prior to participation in this study, each subject must sign an informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

30

Total final enrolment
24

Key exclusion criteria
Active or uncontrolled cardiovascular disease as follows:
a. Coronary artery disease (CAD) (known CAD with previous diagnosis of definite acute myocardial infarction, unstable angina or stable angina)
b. Arrhythmia (uncontrolled, highly symptomatic, requires treatment or life-threatening)
c. Congestive heart failure (CHF) (New York Heart Association function class III and IV - symptoms of heart failure on less than ordinary exertion or at rest)
d. Stroke or transient ischemic attack with residual neurological damage
e. Uncontrolled hypertension: systolic blood pressure (SBP) >180 mmHg or diastolic blood pressure (DBP) >105 mmHg (two abnormal readings during visit)
f. Hypotension
2. Liver disease (alanine aminotranferease (ALT), aspartate aminotransferase (AST), alkaline phosphate levels >2 times upper normal limit) at the time of enrolment
3. Renal disease (macro-albuminuria) (2 of 3 urine specimens collected within a 3-6 month period with urine albumin ≥300 ug/mg creatinine - according to the American Diabetes Association (ADA) position statement)
4. Severe dyslipidemia (triglycerides >600 mg/dl or cholesterol >350 mg/dl). Subjects with hypertriglyceridemia may be re-tested in 2-3 weeks as the values can fluctuate tremendously within a few days. In the event that the re-tested value allows the patient to be enrolled, a planned deviation will be submitted to the Cardiovascular Credentialing International (CCI).
5. Any other serious chronic disease requiring active treatment
6. Females of childbearing potential not using an effective form of birth control as determined by the investigators
7. Subjects on any of the following medications:
a. Angiotensin II receptor antagonist treatment during last 3 months
b. Systemic glucocorticoids
c. Antineoplastic agents
d. Bronchodilators (aminophyline, inhaled beta agonists) on a regular basis
8. Claustrophobia
9. Subjects unable to have magnetic resonance imaging (MRI) scan according to the MRI clinical standards such as a pacemaker, defibrillator, eye implants and other metal implants or devices

Date of first enrolment
26/02/2003

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United States of America

Study participating centre

330 Brookline Avenue
Boston
United States of America
02215

Sponsor information

Organisation
Beth Israel Deaconess Medical Centre (USA)

Sponsor details
330 Brookline Avenue
Palmer 321
Boston
United States of America
02215

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04drvxt59

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009	11/01/2021	Yes	No